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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ANDREAS SEWING,
MICHEL DARD, SOPHIE ROSSLER,
DIETER SCHARNWEBER, and HARTMUT WORCH

Appeal 2009-012778
Application 09/885,287
Technology Center 1600

Decided: June 15, 2010

Before DONALD E. ADAMS, LORA M. GREEN, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to a coated metallic implant. The Examiner rejected the claims for obviousness and obviousness-type double patenting.

We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 1, 3-8, 10, 12-19, 21, and 23-28 are pending and on appeal (App. Br. 2). Claim 1 is representative and reads as follows:

> 1. A coated metallic implant comprising a metallic implant having a surface and an outer layer, wherein the outer layer comprises a bone analogous coating comprising a collagen matrix mineralized with a calcium phosphate phase which is adhered to said implant surface, wherein the mineralized collagen matrix is constructed in the form of layers, whereby at least one of said layers comprises a composite of mineralized collagen fibrils, amorphous calcium phosphate and crystalline hydroxyapatite, wherein the crystals of said crystalline hydroxyapatite have a length of about 300 to 500 nm and wherein said metallic implant is prepared by a process comprising:
>
> a) coating a metallic implant material by immersion in a collagen solution at a pH of less than 8 and a temperature between 4 - 40°C, and
>
> b) coating said metallic implant material with a calcium phosphate phase (CCP) in a[n] electrochemically assisted process by means of cathodic polarization in an electrolyte solution comprising calcium ions and phosphate ions,
>
> wherein process steps a) and b) are performed simultaneously or sequentially.

The Examiner cites the following documents as evidence of unpatentability:

Sauk et al.	US 4,780,450	Oct. 25, 1988
Lussi et al.	US 5,167,961	Dec. 1, 1992
Shirkanzadeh	US 5,205,921	Apr. 27, 1993
Constantz et al.	US 5,279,831	Jan. 18, 1994

Rhee et al.	US 5,543,441	Aug. 6, 1996
Geistlich et al.	US 5,573,771	Nov. 12, 1996
Liu	US 6,300,315 B1	Oct. 9, 2001
Worch et al.	US 6,524,718 B1	Feb. 25, 2003
Story[1] (as translated)	JP 11-047259	Feb. 23, 1999

The claims stand rejected as follows:

(1) Claims 1, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, rejected under 35 U.S.C. § 103 (a) as unpatentable over Story, Constantz, Lussi, and Rhee (Ans. 3-7);

(2) Claims 5, 6, and 26, rejected under 35 U.S.C. § 103(a) as unpatentable over Story, Constantz, Lussi, Rhee, and Sauk (Ans. 7-8);

(3) Claims 7 and 17, rejected under 35 U.S.C. § 103(a) as unpatentable over Story, Constantz, Lussi, Rhee, and Geistlich (Ans. 8-9);

(4) Claim 3, rejected under 35 U.S.C. § 103(a) as unpatentable over Story, Constantz, Lussi, Rhee, and Liu (Ans. 9-10);

(5) Claims 1, 3-5, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, rejected under 35 U.S.C. § 103(a) as unpatentable over Worch, Liu, Lussi, and Rhee (Ans. 10-15);

(6) Claims 6 and 26, rejected under 35 U.S.C. § 103(a) as unpatentable over Worch, Liu, Lussi, Rhee, and Sauk et al (Ans. 15-16);

(7) Claims 1, 3, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, rejected under 35 U.S.C. § 103(a) as unpatentable over Shirkanzadeh, Liu, Lussi, and Rhee (Ans. 16-20);

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[1] The Evidence Relied Upon section of the Examiner's Answer refers to this document as "SULZER CALCITEK" (Ans. 3).

(8) Claims 5, 6, and 26, rejected under 35 U.S.C. § 103(a) as being unpatentable over Shirkanzadeh, Liu, Lussi, Rhee, and Sauk (Ans. 20-21);

(9) Claims 7 and 17, rejected under 35 U.S.C. § 103(a) as unpatentable over Shirkanzadeh, Liu, Lussi, and Rhee, and Geistlich (Ans. 22);

(10) Claims 1, 3-6, 8, 10, 12-16, 18, 19, 23-25, 27, and 28, rejected under 35 U.S.C. § 103(a) as unpatentable over Constantz, Liu, Lussi, and Rhee (Ans. 22-25);

(11) Claims 5, 6, and 26, rejected under 35 U.S.C. § 103(a) as unpatentable over Constantz, Liu, Lussi, Rhee, and Sauk (Ans. 25-26); and

(12) Claims 1, 3-5, 8, 10,[2] 12-16, 18, 19, 21, 23-25, 27, and 28 under the doctrine of obviousness-type double patenting over claims 1-23 of Worch in view of Liu and Lussi (Ans. 27-31).

We affirm rejections (1) through (4), (10), and (11). However, we reverse rejections (5) through (9) and (12).

OBVIOUSNESS -- STORY, CONSTANTZ, LUSSI, AND RHEE

ISSUE

The Examiner rejected claims 1, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, as obvious over Story, Constantz, Lussi, and Rhee (Ans. 3-7).

The Examiner cites Story as evidence that coating metallic prosthetic implants with hydroxyapatite was known in the art, and cites Constantz as evidence that collagen was known in the art to be mixed with hydroxyapatite coatings for prosthetic implants (*id.* at 3-4). The Examiner notes that Constantz and Lussi disclose the use of hydroxyapatite particles of the

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[2] The Examiner's Answer included canceled claim 11 among the claims subject to this ground of rejection.

claimed size for use in implants (*id.* at 4-5), and cites Rhee as evidence that collagen coatings containing mineral components were known in the art to form phases or layers (*id.* at 7).

Appellants argue that by combining Story and Constantz, a skilled artisan "would arrive at a substrate coated by a coating consisting of a simple mixture of hydroxyapatite (with extremely small amounts of amorphous calcium phosphate) and collagen" (App. Br. 15). In contrast, Appellants argue, claim 1 requires the claimed implant to be coated with a "mineralized collagen matrix" which, as disclosed in the Specification is biomimetically produced, and, as shown by other evidence, is a composition that has physical properties different from those that would result from the coating suggested by the references (*id.* at 5-14). Appellants further urge that the cited references do not suggest an implant having the claimed features (*id.* at 14-17).

Appellants do not present separate argument with respect to any of the claims subject to this ground of rejection. We select claim 1 as representative of the rejected claims. *See* 37 C.F.R. § 41.37(c)(1)(vii).

Thus, in view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the evidence of record supports the Examiner's conclusion that an ordinary artisan would have considered an implant having the features recited in claim 1 prima facie obvious in view of the cited references.

FINDINGS OF FACT ("FF")

1. Constantz discloses:

> Methods and compositions are provided relating to hydroxyapatite, particularly as coatings on devices which interact with bone or provide for bone ingrowth. The coatings

> are produced in a multistep process which provides for a strong adherent uniform thin coating of hydroxyapatite on a substrate surface, where the coating has long needles or whiskers, which appear to induce bone ingrowth and strong bonding between natural bone and the coating via bone ingrowth and opposition on a pore comprising implant.

(Constantz, col. 2, ll. 28-37.)

2. Constantz discloses:

> The method involves applying at least two layers, a first layer of very small crystals achieved by providing conditions which result in a high density of heterogeneous nucleation sites, so that there is a large number of hydroxyapatite nucleation sites on the substrate. This is followed by at least one additional coating under conditions which provide for a lower level of nucleation modulated crystal growth, so as to produce substantially larger crystals. Desirably, one or more additional coatings are provided, where the conditions are the same or at even lower levels of nucleation than the second coating to produce larger size crystals as compared to the second coating.

(*Id.* at col. 3, ll. 24-38.)

3. Constantz discloses:

> The first layer will generally be of a thickness in a range of about 0.01 micron to 20 microns, with crystal size in a range of about 0.01 microns to 10 microns. The second coating will generally be of a thickness in a range of about 1 micron to 40 microns, with crystals of a size in the range length of about 0.01 microns to 20 microns.

(*Id.* at col. 3, ll. 39-45.)

4. Constantz discloses that the prostheses are coated by being immersed in a preferably turbulently flowing aqueous "reaction mixture [which] is prepared by bringing together at an elevated temperature and at a mildly

acidic to mildly basic pH, a water soluble calcium source and a water soluble phosphate source" (*id.* at col. 4, ll. 15-18).

5. Constantz discloses:

> The subject coatings may be combined with a wide variety of materials, *such as collagen*, bone growth factors, such as TGF-B, bone morphogenetic factor, combinations thereof, or the like. The growth factors may serve to enhance the growth of osteoblasts, while the growth factors *and collagen may enlist bony ingrowth*. These factors may be included in the reaction mixture or in a storage solution.

(*Id.* at col. 5, l. 67 through col. 6, l. 6 (emphasis added).)

6. Constantz discloses that its coatings are useful on "[v]arious implant devices, for example, the femoral component of a total hip arthroplasty . . . where the devices may be composed of a wide variety of materials, particularly metals or hardened plastics" (*id.* at col. 6, ll. 14-17).

7. Story discloses "dental implants and orthopedic prostheses with a highly crystalline hydroxylapatite (HA) coating" (Story [0020]).

8. Story discloses:

> The implant is first coated with HA using any well known plasma spraying technique. After the implant has been plasma-sprayed with HA, it is subjected to a two-step method consisting of a hydrothermal treatment step and a leaching step. These two steps can be used to obtain an implant with a highly crystalline HA coating containing only a small percentage of amorphous calcium phosphate (ACP).

(*Id.*)

9. Story discloses that plasma spraying involves the use of high temperatures (*id.* at [0006]), as does its hydrothermal treatment (*id.* at [0012]).

10. Lussi discloses "a bone mineral for use in medicine having substantially the crystal structure and mineral microstructure of natural bone permitting physiologically controlled, cell mediated remodelling on implantation" (Lussi, col. 4, ll. 17-21).

11. "The bone mineral produced by the process of [Lussi's] invention is a white, chalky, brittle material, showing the macrosttucture [sic] of the original bone" (*id.* at col. 3, l. 67, through col. 4, l. 1).

12. Lussi discloses:

> The bone mineral according to the invention may thus be used as a remodelling implant or prosthetic bone replacement, for example in orthopedic surgery, including hip revisions, replacement of bone loss e.g. in traumatology, remodelling in maxillo facial surgery or filling periodontal defects and tooth extraction sockets. In this context, the bone mineral may have adsorbed or absorbed therein one or more physiologically active substances.

(*Id.* at col. 4, ll. 32-40.)

13. Lussi's implantable material is made by grinding up vertebrate bones, such as bovine femurs, degreasing with organic solvent, treating with an amine solution at temperatures up to 200° C, and then dry heating at temperatures up to 600° C (*see id.* at col. 2, l. 21 through col. 3, l. 66).

14. Lussi discloses:

> It has been found that while it is important in most instances to avoid significant modification of the size of the bone mineral crystallites, in order to ensure that the bone pieces when implanted, are readily converted into natural bone, there are certain environments, notably the highly vascularised maxillo facial region, where there may be some benefit in slight modification of the structure of the bone mineral to delay unduly rapid resportion (sic]. We have found that in this

> context it may be beneficial to increase the temperature of the final heating step to above 600° C., namely to a temperature between 600° and 700°C. Over this temperature range, there is modest increase in crystal platelet size and an increase in pore size. It is possible in this way to provide the surgeon with a range of bone mineral prosthetic products having different physical and physiological properties, by varying the temperature of the final heating step.

(*Id.* at col. 5, ll. 18-36.)

15. Lussi discloses that a crystal size of 20 to 250 nm (650° C), 100 to 300 nm (700° C), or 100 to 400 nm (800° C), can be obtained depending on heat treatment (*id.* at col. 7, ll. 10-30 (Table 1)).

PRINCIPLES OF LAW

In *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question. The Court accordingly advised that the analysis under § 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418.

The Court also reaffirmed that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976)).

Thus, as the Federal Circuit has stated, "[i]n cases involving overlapping ranges, we and our predecessor court have consistently held that

even a slight overlap in range establishes a *prima facie* case of obviousness." *In re Peterson,* 315 F.3d 1325, 1329 (Fed. Cir. 2003).

The Federal Circuit has also advised that "the discovery of an optimum value of a variable in a known process is usually obvious." *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1368 (Fed. Cir. 2007). In general, however, "an applicant may overcome a *prima facie* case of obviousness by establishing 'that the [claimed] range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.'" *In re Peterson,* 315 F.3d at 1330 (quoting *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997).

With respect to product-by-process claims, it is "well settled that the presence of process limitations in product claims, which product does not otherwise patentably distinguish over the prior art, cannot impart patentability to that product." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1318 (Fed. Cir. 2006). As stated in *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citations omitted):

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.

Also, once the Examiner establishes that a product recited in terms of its process of making is prima facie unpatentable due to anticipation or obviousness, Appellants bear the burden of proving "that the prior art products do not necessarily or inherently possess the characteristics of his

claimed product." *Id.* at 698 (quoting *In re Fitzgerald,* 619 F.2d 67, 70 (CCPA 1980); *In re Best,* 562 F.2d 1252, 1255 (CCPA 1977)).

Lastly, it is well settled that argument by counsel is no substitute for actual evidence. *In re Geisler*, 116 F.3d at 1471.

ANALYSIS

We are not persuaded that the Examiner's conclusion of obviousness with respect to claim 1 lacks support in the evidence of record.

Claim 1 recites a metallic implant that has a bone analogous coating. The coating includes a collagen matrix mineralized with a calcium phosphate phase which is adhered to the implant surface.

The mineralized collagen matrix of claim 1 must be in the form of layers. At least one of the layers has a composite of mineralized collagen fibrils, amorphous calcium phosphate and crystalline hydroxyapatite. The hydroxyapatite crystals must have a length of about 300 to 500 nm.

Claim 1 also recites that the implant is prepared by a process including the steps of (a) coating the metallic implant material by immersing it in a collagen solution at a pH of less than 8 and a temperature between 4 - 40°C, and (b) coating the implant material with a calcium phosphate phase (CCP) in an electrochemically assisted process using cathodic polarization in an electrolyte solution that contains calcium ions and phosphate ions. Claim 1 states that steps (a) and (b) may be performed simultaneously or sequentially.

As claim 1 requires, Constantz discloses a hydroxyapatite crystal-containing coating in the form of layers that can be applied to metallic implants by immersing the implant in a solution that contains calcium ions and phosphate ions (FF 1-4, 6). The broad range of crystal

lengths disclosed by Constantz, 0.01 to 20 microns (10 to 20,000 nm) (FF 3), entirely overlaps claim 1's crystal length range of 300 to 500 nm, thus rendering the claimed crystal length prima facie obvious.

As also required by claim 1, Constantz discloses that the coating can contain collagen to "enlist bony ingrowth," the collagen being included in the coating reaction mixture (FF 5). While it is acknowledged that Constantz does not provide any specific working examples of collagen in its coating layers, because Constantz's coating is applied by immersion, we find that an ordinary artisan would reasonably have interpreted Constantz as suggesting simultaneous application of the hydroxyapatite and collagen to the implant.

Accordingly, we agree with the Examiner that Constantz, at the very least, suggests an implant coated with a layer composed of the collagen/hydroxyapatite composite recited in claim 1. We acknowledge, however, that Constantz's coating methods do not include cathodically polarizing the metallic implant, as recited in step (b) of claim 1.

Nonetheless, given that steps (a) and (b) of claim 1 both involve immersion in a coating solution, the same method used by Constantz, we find it reasonable to conclude that an implant prepared by the methods suggested by Constantz would have the same properties as an implant prepared by the claimed methods, including the same crystalline and amorphous forms, despite the fact that claim 1's step (b) involves electrochemical assistance in addition to immersion in the ion-containing solution.

Appellants, to the contrary, contend that the mere admixture of collagen and hydroxyapatite suggested by the cited prior art is different than

the "mineralized collagen matrix" recited in claim 1 (App. Br. 5-14). We are not persuaded, however, that Appellants have carried their burden in demonstrating that the claimed methods of preparation result in a different product than the one the prior art suggested.

While Appellants urge that the Specification provides evidence that "mineralized collagen matrix" means that the coating is "biomimetically produced and bone analogous" (*id.* at 6), Appellants point to no specific attributes of the coating, other than its production by steps (a) and (b) in claim 1, that distinguish it from the admixture suggested by Constantz.

Similarly, while we acknowledge the Examiner's citation of the "Du" reference in the appealed rejection (Non-Final Rejection 8 (February 8, 2008)), as well as Appellants' argument regarding that reference (App. Br. 7-9), our review of the record does not reveal a copy of the Du reference. Moreover, to the extent Appellants argue (*id.* at 8) that the Du reference shows that claim 1's "mineralized collagen matrix" requires a specific crystal size, as discussed above, Constantz discloses that its coating can contain hydroxyapatite crystals of the claimed length (FF 3).

To support their argument that the claimed product is structurally different than the product suggested by Constantz, Appellants submit Figures 1 and 2, reproduced below (App. Br. 10, 12):

Figure 1

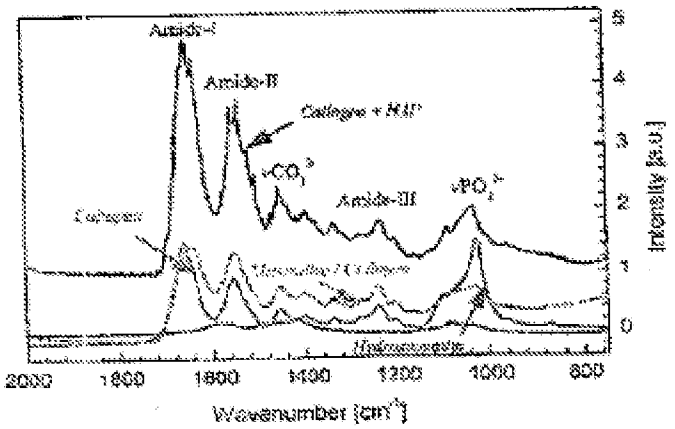

Figure 2

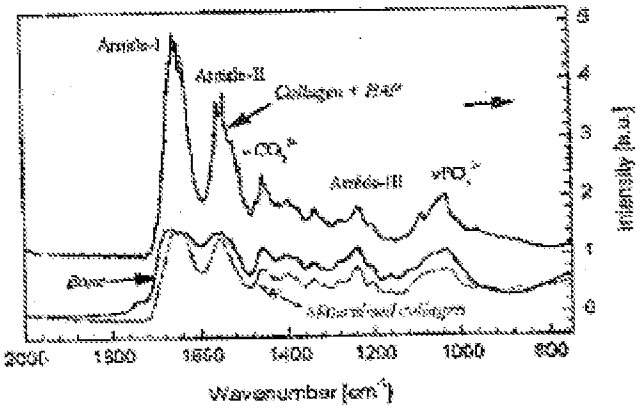

Figure 1 is said to show the Fourier Transform Infrared (FTIR) spectra of (a) collagen, (b) hydroxyapatite, (c) "a mixture of collagen and hydroxyapatite ('Collagen + HAP') which was manufactured by mixing hydroxyapatite particles and collagen and subsequent freeze-drying according to a process similar to that described in US 5,246,457," and (d) "a

mineralized collagen matrix according to the invention ('mineralized Collagen')" (App. Br. 10-11).

Figure 2 is said to show (a) a mixture of collagen and hydroxyapatite ("Collagen + HAP") which was manufactured by mixing hydroxyapatite particles and collagen and subsequent freeze-drying according to a process similar to that described in US 5,246,457, (b) bone, and (c) a mineralized collagen matrix "according to the invention" (*id.* at 12-13).

However, while Appellants state that Figure 1 was "previously present[ed]" (*id.* at 10), Appellants do not state when either of the Figures was submitted, and our review of the record does not indicate that this data was ever presented to the Examiner before appeal. Moreover, other than the statements by counsel in the Appeal Brief and Reply Brief, Appellants point to no evidence of record, in the form of an affidavit or declaration, explaining who prepared the Figures, or how, specifically, the experiments were performed, or what the data shown in the figures would actually mean to an ordinary artisan.

As noted above, argument by counsel is not an adequate substitute for evidence. *In re Geisler*, 116 F.3d at 1471. Accordingly, absent some explanation, beyond that currently of record, regarding the source and import of the evidence proffered in Figures 1 and 2, and when that evidence was entered into the record, we are not prepared to accord the data evidentiary weight. We are therefore also not persuaded that Appellants have demonstrated a structural difference between a product prepared by the process recited in claim 1, and the product suggested by Constantz.

We acknowledge, as Appellants argue, that Story discloses the use of plasma spraying to the coat implants, with no disclosure of collagen in the

coating (App. Br. 14-15). We also note, as Appellants argue, that plasma coating involves high temperatures (FF 9) which an ordinary artisan might not find useful when applying a collagen-containing coating such as Constantz's (Reply Br. 2).

We are not persuaded, however, that any direct incompatibility between the methods of Story and Constantz renders the product recited in claim 1 non-obvious. As the Supreme Court has noted, a "person of ordinary skill is . . . a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421.

Thus, a person of ordinary skill in the art prompted by Story to coat prosthetic implants with hydroxyapatite, aware of the high temperatures used in plasma coating, would have avoided that technique when applying the collagen-containing coating of Constantz. In this regard we note that claim 1 explicitly states that the hydroxyapatite and collagen coating steps can be performed sequentially or simultaneously.

We also do not agree that Lussi would have dissuaded an ordinary artisan from using hydroxyapatite crystals of the claimed size in Constantz's coating. Rather, given Lussi's disclosure that different crystal sizes of implantable bone-compatible material were desirable depending on the intended application of the material (FF 14), combined with Constantz's disclosure that a broad range of crystal sizes was useful in its coating (FF 3), we find that it was reasonable to conclude that the claimed crystal length would have been arrived at through routine optimization.

In sum, Appellants' arguments do not persuade us that the Examiner erred in concluding that an ordinary artisan would have considered the product recited in claim 1 prima facie obvious in view of the cited

references, in particular Constantz. As we find that Appellants have not presented evidence showing that the product recited in claim 1 is different than the product suggested by the references, we affirm the Examiner's rejection of claim 1 over Story, Constantz, Lussi, and Rhee.

Claims 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28 fall with claim 1, as they were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS --

STORY, CONSTANTZ, LUSSI, RHEE, AND SAUK

ISSUE

The Examiner rejected claims 5, 6, and 26 as obvious over Story, Constantz, Lussi, Rhee, and Sauk (Ans. 7-8).

Claim 5 is representative of the rejected claims and recites "[a] coated metallic implant according to Claim 1, wherein the collagen is collagen of type I." The Examiner cited Sauk as evidence that it would have been obvious to include collagen type I in a prosthetic coating of the type disclosed by Constantz (*id.*).

Appellants argue that Sauk, like Story, Constantz, and Lussi, does not teach the electrochemical coating method recited in claim 1, and therefore does not remedy the other references' failures to meet claim 1's requirement of a mineralized collagen matrix (App. Br. 18).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner's conclusion of obviousness with respect to claim 5 is supported by the evidence of record.

FINDINGS OF FACT

16. Sauk discloses "a solid composition which is prepared by a process comprising mixing a phosphophoryn calcium salt and type I collagen" (Sauk, col. 2, ll. 11-13).

17. Sauk also discloses using the compositions to "promote bone formation upon their introduction into osseous defects. It is believed that the particulate calcium phosphate ceramics will enhance the long-term repair and remodeling of new bone in osseous defects over that obtainable with implant compositions consisting essentially of phosphophoryn calcium or phosphophoryn calcium-collagen" (*id.* at col. 2, ll. 30-36).

ANALYSIS

We are not persuaded that the Examiner's conclusion of obviousness lacks support in the cited prior art. As discussed above, while we acknowledge that Constantz's prosthesis is not coated by the electrochemical process recited in step (b) of claim 1, the method of coating by immersion disclosed by Constantz is sufficiently similar to the steps recited in claim 1 such that an ordinary artisan would expect the product suggested by Constantz to be the same or substantially similar to a product made by the process recited in claim 1. As also discussed above, Appellants have not properly presented evidence demonstrating error in that conclusion.

Also, in view of Sauk's teaching of the suitability of collagen I in implantable bone-compatible compositions (FF 16-17), we detect no error in the Examiner's conclusion that it would have been obvious to use collagen type I in Constantz's collagen-containing implant coating. Accordingly, we affirm the Examiner's obviousness rejection of claim 5 over Story,

Constantz, Lussi, Rhee, and Sauk, as well as claims 6 and 26, which were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS --

STORY, CONSTANTZ, LUSSI, RHEE, AND GEISTLICH

ISSUE

The Examiner rejected claims 7 and 17 as obvious over Story, Constantz, Lussi, Rhee, and Geistlich (Ans. 8-9).

Claim 7 recites "[a] coated metallic implant according to Claim 1, wherein said coating further contains gelatin." The Examiner cited Geistlich as evidence that it would have been obvious to include gelatin in a coating for an implantable prosthesis (*id.*).

Appellants contend that Geistlich does not remedy the previously argued deficiencies of Story, Constantz, and Lussi vis-à-vis claim 1, and further argue that, since Geistlich is directed to a bone mineral-containing remodeling implant, as opposed to coatings formed from calcium and phosphate ion-containing solutions, Geistlich would not have prompted an ordinary artisan to include gelatin in a prosthetic coating (App. Br. 18-19).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner's conclusion of obviousness with respect to claim 7 is supported by the evidence of record.

FINDINGS OF FACT

18. Geistlich discloses "a purified particulate bone mineral product for use in medicine . . . having at least at the surface thereof resorbable, physiologically compatible, natural or synthetic macromolecular material" (Geistlich, col. 2, ll. 5-10).

19. Geistlich discloses that the "macromolecular material may be a protein such as gelatin or collagen, which may be cross-linked to give additional strength and freedom from antigen[i]city" (*id.* at col. 2, ll. 23-25).

20. Geistlich discloses that its product can be used as "a remodelling implant or prosthetic bone replacement, for example in orthopoedic surgery, including hip revisions, replacement of bone loss, e.g. in traumatology, remodelling in maxillo-facial surgery or filling periodontal defects and tooth extraction sockets, including ridge augmentation" (*id.* at col. 2, ll. 54-59).

ANALYSIS

We are not persuaded that the Examiner's conclusion of obviousness lacks support in the cited prior art. In particular, given Geistlich's teaching of the usefulness of gelatin in collagen-containing implantable bone-compatible compositions (FF 18-20), we are not persuaded that the Examiner erred in concluding that it would have been obvious to include gelatin in a collagen-containing implant coating such as that disclosed by Constantz. Accordingly, we affirm the Examiner's obviousness rejection of claims 7 and 17 over Story, Constantz, Lussi, Rhee, and Geistlich.

OBVIOUSNESS --

STORY, CONSTANTZ, LUSSI, RHEE, AND LIU

ISSUE

The Examiner rejected claim 3 as obvious over Story, Constantz, Lussi, Rhee, and Liu (Ans. 9-10).

Claim 3 recites "[a] coated metallic implant according to Claim 1, wherein the calcium phosphate phase of the matrix further contains octacalcium phosphate . . . , brushite . . . or mixtures thereof." The

Examiner cited Liu as evidence that it would have been obvious to include octacalcium phosphate in a coating for a prosthesis (*id.*).

Appellants contend that Liu's calcium phosphate-containing collagen membrane is prepared by a method that results in immediate precipitation of the calcium phosphate, which results in a very loose network of calcium phosphate crystals and collagen fibrils, which in turn cannot be used in an electrochemical process such as that recited in claim 1 (App. Br. 20). Accordingly, Appellants argue, following the teachings in Liu "would not provide a coated implant according to the invention" (*id.*).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner's conclusion of obviousness with respect to claim 3 is supported by the evidence of record.

FINDINGS OF FACT

21. Liu discloses a "mineralized collagen membrane useful for medical applications [which] comprises a substantially homogeneous mineralized collagen composite consisting essentially of . . . a collagen component and . . . a calcium phosphate minerals component precipitated from a collagen slurry by a soluble calcium ion-containing solution and a soluble phosphate ion-containing solution" (Liu, col. 2, ll. 54-61).

22. Liu discloses:

> Preferably, the steps of forming a soluble calcium ion-containing solution and a soluble phosphate ion-containing solution includes forming these solutions so that the mineralized collagen membrane comprises about 30% to about 70% calcium phosphate minerals and about 30% to about 70% collagen. The soluble calcium ion-containing solution and the soluble phosphate ion-containing solution are formed so that

> the calcium phosphate minerals comprise calcium phosphate, tri-calcium phosphate, octa-calcium phosphate, calcium deficient apatite, amorphous calcium phosphate, hydroxyapatite, substitute apatite, apatite-like minerals, or a mixture thereof.

(*Id.* at col. 3, ll. 36-48.)

23. Liu discloses that medical applications for its product include "membrane barriers for GTR applications for repairing periodontal defects, membranes for covering bone defect surgery and for bone substitutes, skin wound repair and healing, skin sealing, and as a carrier for antibiotic, bone growth factors, skin growth factors, and so forth" (*id.* at col. 7, ll. 44-49).

ANALYSIS

We are not persuaded that the Examiner's conclusion of obviousness lacks support in the cited prior art. In particular, given Liu's teaching of the usefulness of octacalcium phosphate in collagen-containing implantable bone-compatible compositions (FF 21-23), we conclude that an ordinary artisan would have considered it obvious to prepare a mineralized collagen-containing implant coating, such as that disclosed by Constantz, using a method such as Liu's that would result in octacalcium phosphate in the coating composition.

While Appellants assert that a product made in that way would not be the same as a product made by the process recited in claim 1, as noted above, Appellants have not properly presented evidence supporting that assertion. Accordingly, we affirm the Examiner's obviousness rejection of claim 3 over Story, Constantz, Lussi, Rhee, and Liu.

OBVIOUSNESS -- WORCH, LIU, LUSSI, AND RHEE

ISSUE

The Examiner rejected claims 1, 3-5, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, as obvious over Worch, Liu, Lussi, and Rhee (Ans. 10-15).

The Examiner cites Worch as disclosing a metallic substrate having a layered coating that includes a composite inorganic/organic layer with calcium phosphate as the inorganic component and collagen as the organic component (*id.* at 10-11). The Examiner again relies on Liu for the specific calcium phosphate forms recited in the claims, on Lussi for the desirability of the claimed hydroxyapatite crystal length, and Rhee on the inherent formation of layers in collagen coatings (*id.* at 11-15).

Appellants argue, among other things, that the references' combined disclosures do not teach or suggest an implant "coated with a mineralized collagen matrix comprising mineralized collagen fibrils, amorphous calcium phosphate and hydroxyapatite crystals with a length between about 300 to 500 nm" (App. Br. 22).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner has shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500 nm in length obvious in view of the cited references.

FINDINGS OF FACT

24. Worch discloses "a metallic object with a thin polyphase oxide coating and a process for the manufacture thereof. Objects with such an oxide coating exhibit, in addition to advantageous chemical and physical

properties, high biocompatibility and can be used for a range of purposes due to their properties" (Worch, col. 1, ll. 8-12).

25. Worch discloses that its "two-layer oxide coatings . . . may contain inorganic and/or organic phases" in which the "organic component preferably consists of polymer materials, such as collagen" and the "inorganic component is preferably formed of inorganic fiber structures or calcium phosphate phases" (*id.* at col. 2, ll. 35-50).

26. Worch discloses that, upon coating the metallic substrate with the organic or inorganic phases, "[s]imultaneously or subsequently, in an electrochemical process step, the material forming the substrate surface is anodically polarized in an electrolyte solution" (*id.* at col. 3, ll. 7-9).

27. The electrochemical polarization steps results in "an oxide growth at the phase boundary oxide coating/environment, followed by complete or partial integration of the phases at, or in the direct vicinity of, this phase boundary into the newly formed oxide coating" (*id.* at col. 3, ll. 12-15).

PRINCIPLES OF LAW

As noted above, in *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. at 415, the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question. The Court also reaffirmed, however, that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 418.

Rather, as the Court stated:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely

> upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

Ultimately, therefore, as our reviewing court has stated, "[i]n determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

ANALYSIS

We agree with Appellants that the Examiner has not shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500 nm in length obvious in view of the cited references.

In contrast to the Constantz reference discussed above, Worch does not specifically mention that its coating should contain hydroxyapatite crystals, much less crystals of any particular length. We acknowledge Lussi's disclosure that, depending on the degree of heat treatment, an implant material made from ground bone can be manipulated to have certain crystal sizes, which may have different surgical applications (FF 14-15).

The Examiner has not explained, however, how or why an ordinary artisan coating a metallic substrate with a collagen and/or calcium phosphate solution according to Worch's teachings (FF 24-27) would have applied

Lussi's method of heating a ground bone preparation to temperatures upwards of 650° C (FF 14-15) to generate the claimed size of hydroxyapatite crystals. Given Worch's lack of any disclosure regarding hydroxyapatite, much less its crystal length (in contrast to Constantz), we are not persuaded that an ordinary artisan would have considered Lussi's disclosure applicable or relevant to the issues faced by an artisan practicing Worch's teachings.

As the Examiner has not adequately explained how or why an ordinary artisan would have combined the disparate teachings of Lussi and Worch to provide Worch's coating with hydroxyapatite crystals of 300 to 500 nm in length, we reverse the Examiner's rejection of claims 1 and 28, which recite a metallic implant having a coating with such crystals, as well as their dependent claims.

OBVIOUSNESS -- WORCH, LIU, LUSSI, RHEE, AND SAUK

The Examiner rejected claims 6 and 26 under 35 U.S.C. § 103(a) as unpatentable over Worch, Liu, Lussi, Rhee, and Sauk et al (Ans. 15-16). As discussed above, the Examiner relied on Worch, Liu, Lussi, and Rhee as obviating a coated metallic implant as recited in claim 1, and cited Sauk as teaching the desirability of the collagen types recited in claims 6 and 26.

We reverse this rejection as well. As noted above, we do not agree that the combined teachings of Worch, Liu, Lussi, and Rhee suggest a metallic implant coated with hydroxyapatite crystals 300 to 500 nm long, and we see nothing in Sauk's teachings of using type I collagen in bone-compatible implantable compositions (FF 16-17) that remedies that deficiency.

OBVIOUSNESS --

SHIRKANZADEH, LIU, LUSSI, AND RHEE

The Examiner rejected claims 1, 3, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, rejected under 35 U.S.C. § 103(a) as unpatentable over Shirkanzadeh, Liu, Lussi, and Rhee (Ans. 16-20).

The Examiner cites Shirkanzadeh as disclosing a metallic substrate having a layered coating that includes a composite inorganic/organic layer with calcium phosphate as the inorganic component and collagen as the organic component (*id.* at 16-17). The Examiner again relies on Liu for the specific calcium phosphate forms recited in the claims, on Lussi for the desirability of the claimed hydroxyapatite crystal length, and Rhee on the inherent formation of layers in collagen coatings (*id.* at 17-20).

Appellants argue that Shirkanzadeh, among other things, produces coatings with crystal sizes of 2,000 to 20,000 nm, as opposed to the claimed 300 to 500 nm crystal length (App. Br. 24). Moreover, Appellants argue, "Liu is silent regarding a metal surface of a metallic implant and Lussi et al., who uses purified native bone particles, teaches away from selecting the particle size of the instant invention" (*id.* at 25).

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether the Examiner has shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500 nm in length obvious in view of the cited references.

FINDINGS OF FACT

28. Shirkanzadeh discloses a process of coating a metallic implantable prosthesis in which the prosthesis is immersed in an electrolyte solution that

preferably contains "calcium phosphate tribasic ($Ca_{10}(OH)_2$ $(PO_4)_6$) dissolved in hydrochloric acid (about 20g of calcium phosphate/l)" (Shirkanzadeh, col. 2, ll. 26-28).

29. Shirkanzadeh discloses that applying a potential to the electrolyte solution that contains the metal substrate "cathodically polarizes the substrate and reduces the hydrogen ion concentration at the cathode so that at the surface of the cathode the pH of the solution rises to about pH 8-10 and the desired coating such as aluminum oxide and preferably calcium phosphate is precipitated as a dense, adherent film onto the cathode" (*id.* at col. 2, ll. 39-45).

30. Shirkanzadeh discloses that "[t]he electrolyte may also contain organic materials such as proteins and biologically non-toxic compounds such as collagen or impurities" (*id.* at col. 3, ll. 9-12).

31. In Example 1, Shirkanzadeh produces a coated titanium alloy substrate with a coating "composed of an interlocking network of non-oriented platelike crystals" with an average size of about 20 microns (20,000 nm) (*id.* at col. 4, ll. 48-50).

32. In Example 2 Shirkanzadeh's coating consisted of platelike crystals 2 to 5 microns (2,000 to 5,000 nm) in size (*id.* at col. 4, l. 67).

ANALYSIS

We agree with Appellants that the Examiner has not shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500 nm in length obvious in view of the cited references.

We acknowledge that, like step (b) of claim 1, Shirkanzadeh coats a metallic prosthesis with calcium phosphate by cathodically polarizing the

metal substrate (FF 29-30). However, Shirkanzadeh discloses that the crystals deposited onto its metal prostheses range in size from 2,000 to 20,000 nm (FF 32), a much larger size than recited in claim 1.

We also acknowledge Lussi's disclosure that an implant material made from ground bone can be manipulated to have a specific crystal size range, which may be suited to particular surgical applications, with crystal sizes overlapping those claimed achieved by heating the ground bone composition to temperatures upwards of 650° C (FF 14-15). The Examiner points to no teaching in Lussi, however, about using its implantable composition as a prosthetic coating, much less how one would go about doing so.

Thus, the Examiner has not adequately explained how an ordinary artisan would have applied Lussi's teachings to significantly reduce the crystal size of Shirkanzadeh's coating, or explained why an ordinary artisan applying Shirkanzadeh's coating would have been prompted to reduce the applied crystals to 300 to 500 nm in length. Accordingly, we reverse the Examiner's rejection of claims 1 and 28, which recite a metallic implant having a coating with such crystals, as well as their dependent claims.

OBVIOUSNESS --

SHIRKANZADEH, LIU, LUSSI, RHEE, AND SAUK

The Examiner rejected claims 5, 6, and 26, under 35 U.S.C. § 103(a) as being unpatentable over Shirkanzadeh, Liu, Lussi, Rhee, and Sauk (Ans. 20-21).

The Examiner relied on Shirkanzadeh, Liu, Lussi, and Rhee as obviating a coated metallic implant as recited in claim 1, and cited Sauk as

teaching the desirability of the collagen types recited in claims 6 and 26 (*id.* at 21).

We reverse this rejection as well. As noted above, we do not agree that the combined teachings of Shirkanzadeh, Liu, Lussi, and Rhee suggest a metallic implant coated with hydroxyapatite crystals 300 to 500 nm long, and we see nothing in Sauk's teachings of using type I collagen in bone-compatible implantable compositions (FF 16-17) that remedies that deficiency.

OBVIOUSNESS --

SHIRKANZADEH, LIU, LUSSI, RHEE, AND GEISTLICH

The Examiner rejected claims 7 and 17 under 35 U.S.C. § 103(a) as unpatentable over Shirkanzadeh, Liu, Lussi, and Rhee, and Geistlich (Ans. 22).

The Examiner relied on Shirkanzadeh, Liu, Lussi, and Rhee as obviating a coated metallic implant as recited in claim 1, and cited Geistlich as teaching the desirability of the gelatin recited in claims 7 and 17 in implantable bone-compatible compositions (*id.* at 22).

We reverse this rejection as well. As noted above, we do not agree that the combined teachings of Shirkanzadeh, Liu, Lussi, and Rhee suggest a metallic implant coated with hydroxyapatite crystals 300 to 500 nm long, and we see nothing in Geistlich's teachings of using gelatin in bone-compatible implantable compositions (FF 18-20) that remedies that deficiency.

OBVIOUSNESS --

CONSTANTZ, LIU, LUSSI, AND RHEE

The Examiner rejected claims 1, 3-6, 8, 10, 12-16, 18, 19, 23-25, 27, and 28 under 35 U.S.C. § 103(a) as unpatentable over Constantz, Liu, Lussi, and Rhee (Ans. 22-25).

The Examiner cited Constantz as disclosing a layered hydroxyapatite-containing metallic prosthesis coating that can have a broad range of crystal sizes which encompasses the 300 to 500 nm crystal length recited in claim 1 (Ans. 23). The Examiner cited Liu as teaching the use of a variety of calcium phosphate minerals in a collagen-containing membrane used as a bone substitute, Lussi for the desirability of the claimed particle size, and Rhee for the inherent presence of layers in mineralized collagen compositions (*id.* at 23-25).

Appellants again argue that the simple admixture-type coating resulting from immersing a prosthesis in a solution containing calcium phosphate and collagen is structurally different from the mineralized collagen matrix produced by the electrochemically assisted method recited in claim 1 (App. Br. 28). Moreover, Appellants argue, none of the cited references directs an ordinary artisan to the claimed crystal length, and Lussi and Rhee teach away from the claimed coating (*id.*).

Appellants' arguments do not persuade us that the Examiner failed to make a prima facie case of obviousness. As discussed above, we agree with the Examiner that Constantz suggests an implant coated with a layer composed of the collagen/hydroxyapatite composite recited in claim 1. Given the overlap between Constantz's crystal lengths and the range recited

in claim 1, we agree with the Examiner that the claimed crystal length would have been obvious in view of Constantz.

As also discussed above, because Constantz's prosthesis is coated by immersion in a solution containing the same salts recited in claim 1, we find that the Examiner was reasonable in concluding that an implant prepared by Constantz's methods would have the same properties as an implant prepared by the claimed methods, including the same crystalline and amorphous forms. As further discussed above, Appellants have not properly presented evidence demonstrating error in the Examiner's conclusion that a prosthesis coated according to Constantz's suggested procedures would be unobviously different from that produced by the claim-recited processes.

Moreover, we see nothing in the disclosures of Liu, Lussi, and Rhee that would have dissuaded an ordinary artisan from following Constantz's teachings and preparing a coated implant having the properties of the implant recited in claim 1. Accordingly, we affirm the Examiner's rejection of claim 1 as obvious over Constantz, Liu, Lussi, and Rhee.

Claims 3-6, 8, 10, 12-16, 18, 19, 23-25, 27, and 28 fall with claim 1 as they were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS --

CONSTANTZ, LIU, LUSSI, RHEE, AND SAUK

The Examiner rejection claims 5, 6, and 26 under 35 U.S.C. § 103(a) as unpatentable over Constantz, Liu, Lussi, Rhee, and Sauk (Ans. 25-26). The Examiner cited Sauk as evidence that it would have been obvious to include the various types of collagen, including collagen type I, as recited in claim 5, in a collagen-containing prosthetic coating (*id.* at 26).

Appellants argue that Sauk, like Liu, Lussi, and Rhee, does not teach the electrochemical coating method recited in claim 1, and therefore does not remedy the other references' failures to meet claim 1's requirement of a mineralized collagen matrix (App. Br. 29-30).

We have considered all of Appellants' arguments but do not find them persuasive. As discussed above, Appellants have not properly presented evidence demonstrating error in the Examiner's conclusion that a prosthesis coated according to Constantz's suggested procedures would be unobviously different from that produced by the claim-recited processes.

As also discussed above, in view of Sauk's teaching of the suitability of collagen I in implantable bone-compatible compositions (FF 16-17), we detect no error in the Examiner's conclusion that it would have been obvious to use collagen type I in Constantz's collagen-containing implant coating. Accordingly, we affirm the Examiner's obviousness rejection of claim 5 over Constantz, Liu, Lussi, Rhee, and Sauk, as well as claims 6 and 26, which were not argued separately. *See* 37 C.F.R. § 41.37(c)(1)(vii).

OBVIOUSNESS-TYPE DOUBLE PATENTING

ISSUE

Claims 1, 3-5, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28 stand rejected under the doctrine of obviousness-type double patenting over claims 1-23 of Worch in view of Liu and Lussi (Ans. 27-31).

The Examiner finds that the claims of Worch recite a metallic prosthesis with a polyphase organic/inorganic (collagen/calcium phosphate) coating and cites Liu to meet the rejected claims' requirements for collagen types I, II, and/or III, and cites Lussi to demonstrate the obviousness of the crystal lengths recited in the rejected claims (*id.*).

Appellants contend that the cited references, among other things, fail to teach or suggest a coating as claimed, "wherein the crystals of said crystalline hydroxyapatite have a length of about 300 to 500 nm" (App. Br. 31).

The issue regarding this rejection, therefore, is whether the Examiner has shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500 nm in length obvious over claims 1-23 of Worch in view of Liu and Lussi.

FINDINGS OF FACT

33. Claims 1-23 of Worch recite a metallic object with a polyphase coating in which the organic phase may be collagen (Worch, col. 5, ll. 42-44 (claim 3)) and the inorganic phase may be calcium phosphate (*id.* at col. 5, ll. 45-47 (claim 4)), and also recite a process whereby the coating is applied using an electromagnetic field (*id.* at col. 6, l. 29-32 (claim 13)).

34. Claims 1-23 of Worch do not recite any crystal length for any hydroxyapatite that might be precipitated onto the metal object.

PRINCIPLES OF LAW

In obviousness-type double patenting rejections, the Examiner must establish, in an analysis comparable to that under 35 U.S.C. § 103, that one of ordinary skill would have considered the rejected claims obvious over the conflicting claims. *See In re Braat*, 937 F.2d 589, 592-93 (Fed. Cir. 1991).

ANALYSIS

We agree with Appellants that the Examiner has not shown that an ordinary artisan would have considered an implant coated with a mineralized collagen matrix having hydroxyapatite crystals between about 300 to 500

nm in length obvious over Worch's claims when viewed in light of Liu and Lussi.

As noted above, Worch's claims do not explicitly state that the patented coating should contain crystals, much less crystals of any particular length. As discussed above, while Lussi discloses that an implant material made from ground bone can be manipulated to have certain crystal sizes, the Examiner has not adequately explained why ordinary artisan electrochemically applying a coating to a metal object as recited in Worch's claims would have found in Lussi either the methodology or the incentive to manipulate any crystals that might result from the coating process to achieve the claimed crystal length.

Accordingly, we reverse the Examiner's obviousness-type double patenting rejection of claims 1 and 28, which both recite crystal lengths of 300 to 500 nm, as well as the rejection over their dependent claims.

SUMMARY

We affirm the Examiner's rejection of claims 1, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, under 35 U.S.C. § 103(a) over Story, Constantz, Lussi, and Rhee.

We also affirm the Examiner's rejection of claims 5, 6, and 26, under 35 U.S.C. § 103(a) Story, Constantz, Lussi, Rhee, and Sauk.

We also affirm the Examiner's rejection of claims 7 and 17, under 35 U.S.C. § 103(a) over Story, Constantz, Lussi, Rhee, and Geistlich.

We also affirm the Examiner's rejection of claim 3 under 35 U.S.C. § 103(a) over Story, Constantz, Lussi, Rhee, and Liu.

We affirm the Examiner's rejection of claims 1, 3-6, 8, 10, 12-16, 18, 19, 23-25, 27, and 28, under 35 U.S.C. § 103(a) over Constantz, Liu, Lussi, and Rhee.

We also affirm the Examiner's rejection of claims 5, 6, and 26, under 35 U.S.C. § 103(a) over Constantz, Liu, Lussi, Rhee, and Sauk.

However, we reverse the Examiner's rejection of claims 1, 3-5, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28 under 35 U.S.C. § 103(a) as over Worch, Liu, Lussi, and Rhee.

We also reverse the Examiner's rejection of claims 6 and 26 under 35 U.S.C. § 103(a) over Worch, Liu, Lussi, Rhee, and Sauk.

We also reverse the Examiner's rejection of claims 1, 3, 4, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28, under 35 U.S.C. § 103(a) over Shirkanzadeh, Liu, Lussi, and Rhee.

We also reverse the Examiner's rejection of claims 5, 6, and 26, under 35 U.S.C. § 103(a) over Shirkanzadeh, Liu, Lussi, Rhee, and Sauk.

We also reverse the Examiner's rejection of claims 7 and 17 under 35 U.S.C. § 103(a) over Shirkanzadeh, Liu, Lussi, and Rhee, and Geistlich.

We also reverse the Examiner's rejection of claims 1, 3-5, 8, 10, 12-16, 18, 19, 21, 23-25, 27, and 28 under the doctrine of obviousness-type double patenting over claims 1-23 of Worch in view of Liu and Lussi.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc

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